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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,179	03/23/2006	Wataru Kubo	03500.119219.	6626

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EXAMINER	
GRAHAM, CHRISTOPHER R	
ART UNIT	PAPER NUMBER
1795	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,179	KUBO ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER R. GRAHAM	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/03/2007, 12/14/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 8, (p. 85, line 13) cites the limitation, "the *second* mediator has a redox potential more positive than the redox potential of the *second* mediator." It is impossible for the exact same second redox mediator to have two different redox potentials, which renders claim 8 indefinite. For the purposes of applying prior art, the examiner will presume that claim 8 was meant to include the first redox mediator so that the claim should read, "the ***first*** mediator has a redox potential more positive than the redox potential of the *second* mediator."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman et al (U.S. patent 6,299,757, hereafter referred to as Feldman) in view of Nanba et al. (U.S. patent 5,236,567, hereafter referred to as Nanba) and further in view of Guo et al. (U.S. Patent 6,033,866, hereafter referred to as Guo).

Regarding claim 1, Feldman teaches an enzyme electrode comprising a conductive member (conducting layer or electrode surface, see column 27, lines 53-57), a redox mediator and an enzyme (second electron transfer agent, see column 24, lines 18-29), see column 28, lines 20-25. Feldman teaches that the redox mediator can be immobilized onto the electrode surface using a carrier (cross-linking agent), see column 22, lines 47-66. Feldman does not teach the use of two different redox mediators. Feldman does not teach the use of two different redox mediators having different redox potentials.

Nanba teaches an enzyme-modified electrode comprising an electrode, an enzyme and a mediator, see column 1, lines 5-12. Nanba teaches that the enzymne-modified electrode is useful to measuring biological components in the human body, see column 1, lines 15-21. Nanba teaches that an enzyme-modified electrode can be

constructed utilizing two or more different mediators simultaneously, see column 5, lines 64-68 to column 6, lines 1-7.

Guo teaches a glucose biosensor comprising an electrode with an enzyme and first mediator and a reagent strip in contact with the electrode that contains a second mediator, see column 2, lines 23-34. Guo teaches that two different mediators simultaneously in contact with an enzyme and electrode surface provide higher sensitivity and greater linear response to the electrode than when using one mediator alone, see column 2, lines 10-21. The two-mediator electrode system allows the measurement of glucose in serum, plasma, whole blood or urine. see column 2, lines 10-21.

It would have been obvious to one of ordinary skill in the art to use two different mediators (as taught by Nanba) with the enzyme electrode of Feldman. The motivation for using two different mediators on the electrode of Feldman would be higher sensitivity and greater linear response of the electrode, as taught by Guo.

Furthermore, it would also be obvious to one of ordinary skill in the art that two different mediators would likely possess different redox potentials.

Regarding claims 2 and 3, the combination of Feldman, Nanba and Guo does not specifically teach first and second mediators where the first mediator has a more negative redox potential than the second mediator, or where the first mediator has a more positive redox potential than the second mediator. The combination also does not specifically teach an electron transfer rate between the second mediator and the

conductive member (electrode surface) higher then the electron transfer rate between the first mediator and the conductive member (electrode surface).

Nanba teaches that mediators are selected such that an electron transfer proceeds smoothly, see column 5, lines 64-68.

Therefore, it would have been obvious to one of ordinary skill in the art to select two mediators from the extensive list of known mediators (as only partially described by Feldman, see column 15-22) such that the redox potential of the first mediator would be more or less positive than the second mediator and such that the electron transfer rate between the second mediator and the conductive member (electrode surface) would be greater than the electron transfer rate between the first mediator and the conductive member (electrode surface).

One of ordinary skill in the art would be motivated to select the mediators that would allow the highest and quickest transfer of electrons from the enzyme to the electrode surface.

Regarding claim 4, the combination of Feldman, Nanba and Guo does not specifically teach the first mediator transferring electrons to and from the enzyme and the second mediator transferring electrons to and from the first mediator. However, claim 4 is a statement of intended use. The cited prior art teaches all of the *positively recited structure* of the *claimed apparatus*. The Courts have held that a statement of intended use in an apparatus claim fails to distinguish over a prior art apparatus. See *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim

from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP §§ 2114 and 2173.05(g)).

Therefore, the combination of Feldman, Nanba and Guo is capable of the intended use described in claim 4, rendering claim 4 obvious over the prior art.

Regarding claim 6, Feldman teaches the use of metal complexes and quinones as mediators, see column 20, lines 30-55.

Regarding claims 7 and 8, the combination of Feldman, Nanba and Guo does not specifically teach first and second mediators where the first mediator has a more negative redox potential than the second mediator, or where the first mediator has a more positive redox potential than the second mediator.

Nanba teaches that mediators are selected such that an electron transfer proceeds smoothly, see column 5, lines 64-68.

Therefore, it would have been obvious to one of ordinary skill in the art to select two mediators from the extensive list of known mediators (as only partially described by Feldman, see column 15-22) such that the redox potential of the first mediator would be more or less positive than the second mediator.

One of ordinary skill in the art would be motivated to select the mediators that would allow the highest and quickest transfer of electrons from the enzyme to the electrode surface.

The statements of the enzyme employed as an anode and a cathode are statements of intended use. The cited prior art teaches all of the *positively recited structure* of the *claimed apparatus*. The Courts have held that a statement of intended use in an apparatus claim fails to distinguish over a prior art apparatus. See *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP §§ 2114 and 2173.05(g)).

Therefore, the combination of Feldman, Nanba and Guo is capable of the intended use described in claims 7 and 8, rendering claims 7 and 8 obvious over the prior art.

Regarding claim 9, Feldman teaches a biosensor that utilizes an enzyme electrode for the detection of a substance, see Abstract.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman, Nanba and Guo, as applied to claim 1 above, and further in view of Guadalupe et al. (U.S. patent 6,231,920, hereafter referred to as Guadalupe).

Regarding claim 5, the combination of Feldman, Nanba and Guo teaches an enzyme electrode but does not specifically teach the conductive member (electrode surface) being porous.

Guadalupe teaches graphite composites useful for electrodes of glucose sensors, see Abstract. Guadalupe teaches that the graphite electrode can be made porous, see column 5, lines 44-47. Guadalupe teaches that a porous graphite electrode possesses low resistivity, rapid and economical one-step fabrication and a high surface area, See column 5, lines 39-47.

It would have been obvious to one of ordinary skill in the art to use a porous electrode as the conductive member (electrode surface) of Feldman, as taught by Guadalupe. The motivation for the combination would be to reduce the resistivity of the electrode and increase the surface area of the electrode.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman, Nanba and Guo, as applied to claim 1 above, and further in view of Heller (U.S. Patent 6,294,281).

Regarding claim 10, the combination of Feldman, Nanba and Guo teaches an enzyme electrode but does not specifically teach a fuel cell employing the enzyme electrode.

Heller teaches a fuel cell that employs an enzyme electrode (see Abstract) with a single mediator (redox hydrogel) but does not teach an enzyme electrode with two different mediators.

It would have been obvious to one of ordinary skill in the art to use the enzyme electrode of Feldman, combined with Nanba and Guo, as the cathode or anode of the fuel cell of Heller. The motivation would be that the enzyme electrode of Feldman, combined with Nanba and Guo, which would contain two different mediators would produce a higher activity than a cathode or anode with only one mediator.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman, Nanba and Guo as applied to claim 1 above, and further in view of Forrest et al. (U.S. Patent 5,149,630, hereafter referred to as Forrest).

Regarding claim 11, the combination of Feldman, Nanba and Guo teaches an enzyme electrode but does not specifically teach an electrochemical reactor employing the enzyme electrode.

Forrest teaches the use of an enzyme electrode in an electrochemical reactor (cell). Forrest teaches that the enzyme can be immobilized, along with a mediator, onto the electrode surface, see Abstract.

It would have been obvious to one of ordinary skill in the art to use the enzyme electrode of Feldman, combined with Nanba and Guo, in the electrochemical reactor (cell) of Forrest. The motivation for the combination would be the higher activity of the enzyme electrode, resulting from the use of two different mediators on the electrode, over enzyme electrodes using only one mediator.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. GRAHAM whose telephone number is (571)270-7896. The examiner can normally be reached on Monday to Friday 9:30AM-6:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Sines can be reached on (571)272-1263. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. R. G./
Examiner, Art Unit 1795

/Brian J. Sines/

Supervisory Patent Examiner, Art Unit 1795